

Listing of the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. - 15. (canceled)

16. (withdrawn - currently amended) A process for producing a freeze-dried preparation comprising methylcobalamin which comprises the steps of:

(1) dissolving the methylcobalamin or a pharmacologically acceptable salt thereof and an excipient in a solvent, wherein said excipient comprises at least one sugar or sugar alcohol, said sugar being selected from the group consisting of glucose, fructose, maltose, lactose, sucrose and trehalose, ~~and said sugar alcohol being selected from the group consisting of inositol, sorbitol and mannitol~~ wherein the ratio of excipient to methylcobalamin is from 2.5 to 25 parts by weight, based on 1 part by weight of methylcobalamin, and

(2) freeze-drying the solution so as to produce an amorphous state of at least one or more of said sugar ~~or of said sugar alcohol~~ in said excipient wherein said sugar ~~or said sugar alcohol~~ that is in said amorphous state in said excipient is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

17. (withdrawn) The process according to claim 16, wherein the freeze drying in step (2) is performed so as to further produce an amorphous state of the methylcobalamin or the pharmacologically acceptable salt thereof.

18. (withdrawn) The process according to claim 16, wherein pre-freezing during said freeze-drying process in step (2) is performed at a temperature at which the excipient does not crystallize, or below the temperature.

19.-20. (canceled)

21. (withdrawn) The process according to claim 16, wherein the freeze-dried preparation further comprises a pH adjuster.

22. (withdrawn) The process according to claim 16, wherein the freeze-dried preparation further comprises an anti-oxidant.

23. (withdrawn) The process according to claim 16, wherein the excipient comprises both said sugar and said sugar alcohol.

24. -27. (canceled)

28. (currently amended) A freeze-dried preparation comprising methylcobalamin or a pharmacologically acceptable salt thereof and an excipient,

wherein said excipient comprises at least one sugar in an amorphous state, said sugar being selected from the group consisting of glucose, fructose, maltose, lactose, sucrose and trehalose, wherein the ratio of excipient to methylcobalamin is from 2.5 to 25 parts by weight, based on 1 part by weight of methylcobalamin, and

wherein said sugar that is present in said amorphous state is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

29. (canceled)

30. (previously presented) The freeze-dried preparation according to claim 28 or claim 29, further comprising a pH adjuster.

31. (previously presented) The freeze-dried preparation according to claim 28 or claim 29, further comprising an anti-oxidant.

32. (previously presented) The freeze-dried preparation according to claim 30, further comprising an anti-oxidant.

33. (previously presented) The freeze-dried preparation according to claim 28, wherein said methylcobalamin or said pharmacologically acceptable salt thereof is also in an amorphous state.

34. (previously presented) The freeze-dried preparation according to claim 33, wherein said sugar that is present in said amorphous state is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

35. (previously presented) The freeze-dried preparation according to claim 33 or claim 34, further comprising a pH adjuster.

36. (previously presented) The freeze-dried preparation according to claim 33 or claim 34, further comprising an anti-oxidant.

37. (currently amended) A freeze-dried preparation comprising methylcobalamin or a pharmacologically acceptable salt thereof and an excipient, the freeze-dried preparation obtained by a production process which comprises the steps of:

(a) dissolving the methylcobalamin or the pharmacologically acceptable salt thereof and the excipient in a solvent, wherein said excipient comprises at least one sugar, said sugar being selected from the group consisting of glucose, fructose, maltose, lactose, sucrose and trehalose, and wherein the ratio of excipient to methylcobalamin is from 2.5 to 25 parts by weight, based on 1 part by weight of methylcobalamin; and

(b) freeze-drying the solution so as to produce an amorphous state of at least one said sugar in said excipient, and

(c) wherein said sugar that is in said amorphous state is present in said excipient in an amount that is at least 20% by weight, based on the total weight of said excipient.

38. (canceled).

39. (previously presented) The freeze-dried preparation according to claim 37, wherein the freeze-drying in the step (b) is accomplished so as to further produce an amorphous state of the methylcobalamin or the pharmacologically acceptable salt thereof.

40. (previously presented) The freeze-dried preparation according to claim 37 or claim 39, wherein pre-freezing during said freeze-drying process in step (b) is performed at a temperature at which the excipient does not crystallize, or below the temperature.

41. (previously presented) The freeze-dried preparation according to claim 37 or claim 39, wherein a pH adjuster is also dissolved in step (a).

42. (previously presented) The freeze-dried preparation according to claim 37 or claim 39, wherein an anti-oxidant is also dissolved in step (a).

43. (previously presented) The freeze-dried preparation according to claim 28 or claim 37, wherein the residual ratio of said methylcobalamin in said preparation is 95% or more after 6 months' storage at 40 degrees C.